ORIENTAL SYSTEM TECHNOLOGY INC.

EXHIBIT #1

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and CFR§807.92.

The assigned 510(k) number is: K030299 FEB 2 5 2003

1. Submitter's Identifications:

Oriental System Technology Inc.
2F No.23, Industry E, Road 9th,
Science Based Industrial Park
Hsinchu, Taiwan, R.O.C

Contact:

Mr. Herman Lee
General Manager

Date of Summary Preparation: 30 December 2002

2. Name of the Device:

TempTeller® Infrared Ear Thermometers, Model CT-31/31DX/32/32DX

3. Information of the 510(k) Cleared Device (Predicate Device):

TempTeller® Infrared Ear Thermometers, Model CT-30/30DX
510(k) Number: K#010235

4. Device description:

The OSTI TempTeller® Infrared Ear Thermometers, model CT-31/31DX/32/32DX, is an electronic thermometer using an infrared sensor to detect human body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane (eardrum) and the adjacent tissue.

OSTI TempTeller® Infrared Ear Thermometers, model CT-31/31DX/32/32DX, consists mainly of five parts: an IR sensor packed together with an ambient temperature sensor, a waveguide, a heat sink made of zinc alloy, a LCD display and the associated circuit.

The tympanic membrane (eardrum) is thin and flooded with blood at the core temperature. The waveguide, usually a cylindrical pipe with a highly reflective inner surface for confining the radiation, is adaptive to the outer without contacting the eardrum. When inserting the probe into the ear canal, the radiation fluxes transfer among the tympanum membrane (eardrum), the IR sensor, and the inner surface of the waveguide. The ambient sensor is packed with the IR sensor to monitor the ambient temperature of the IR sensor.

To measure core temperature, an ear thermometer is inserted into a patient's outer ear canal. An activation button is pressed to start the measurement through the radiation exchanges. The electrical signal readouts form the IR sensor and the ambient temperature sensor are fed to the circuit for amplification, digitization and calculation. The measured temperature then appears on the LCD. The total operation takes one second.

The CT-31/31DX/32/32DX is identical in functionality and performance with the essential change being the external shape of the devices. The modifications to our original 510(k) cleared device, model CT-30/30DX, include dimensional and firmware. The fundamental scientific technology of the modified device remains the same as that of the 510(k) cleared device.

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect the body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Comparison to Predicate Devices:

The OSTI TempTeller® Infrared Ear Thermometers, model CT-31/31DX/32/32DX are substantially equivalent to OSTI TempTeller® Infrared Ear Thermometers, CT-30/30DX. The new models CT-31/31DX/32/32DX have the same intended use as and are similar in design to the 510(k) cleared device.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards include ASTM E 1965-98 and ASTM E 1104, as well as IEC 601-1-1 and IEC 601-1-2 requirements.

FDA Guidance documents include the" Deciding When to Submit a 510(k) for a Change to An Exiting Device" and "The New 510(k) Paradigm: Alternate

Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

8. Conclusions

The OSTI TempTeller® infrared Ear thermometers, model CT-31/31DX/32/32DX have the same intended use and technological characteristics as the 510(k) cleared device. Moreover, verification and validation tests contained in this submission demonstrate that the modified portions maintained its original safety and effectiveness. Those engineering changes do not: (1) affect the intended use or (2) alter the fundamental scientific of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2003

Oriental System Technology, Incorporated
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
Mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K030299
Trade/Device Name: Oriental System Technology Incorporated Temp Teller® Infrared Ear Thermometer, Model CT-31/31 DX/32/32DX
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 27, 2003
Received: January 29, 2003

Dear Ms. Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT #B

510(K) Number (If known): K030299

Device Name: Oriental System Technology Inc. TempTeller® Infrared Ear Thermometer, Model CT-31/31DX/32/32DX

Indications for Use

The device is an electronic clinical thermometer using an infrared sensor to detect the human body temperature from the auditory canal in the neonatal, pediatric and adult Populations used in the home setting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number 030299

Prescription Use_____ (Per 21 CFR 801.109)

OR

Over-The- Counter Use ✓ (Optional Format 1-2-96)